

## **REMARKS**

### ***Claim Amendments***

Claims 26-35, 42, and 61-76 are pending in the present application. Claims 26, 34, 35, and 69 are currently amended. In particular, Claim 26 is amended to delete the word "first" and to replace the word "portion" with the word "region" in two instances, all in reference to the target nucleic acid, Claims 34 and 35 are amended to replace the term "oligonucleotide" with the term "nucleic acid molecule," and Claim 69 is amended to replace the word "occurring" with the word "occurring." Applicants note that all amendments of Claims presented herein are made for clarity and to replace typographical errors, and are made without acquiescing to any of the Examiner's arguments or rejections. None of the amendments made herein are intended to narrow the scope of any Claim within the meaning of *Festo* or related cases.

In the Office Action mailed on August 28, 2003, the Examiner raised a number of issues. These will be addressed below in the order presented in the above-cited Office Action.

### ***Information Disclosure Statement***

The Examiner asserts that the Information Disclosure Statement filed on January 22, 2003 fails to comply with 37 CFR § 1.98(a)(2), which requires a legible copy of each cited reference to be provided by the Applicants. Applicants respectfully disagree.

As indicated in the New Application Transmittal and the Preliminary Amendment filed with the present application on October 18, 2001, and as acknowledged on the Filing Receipt mailed November, 15, 2001, the present application is a Continuation of U.S. Patent Appl. Ser. No. 09/350,309 (now issued as U.S. Patent No. 6,348,314). According to MPEP 609 (I)(A)(2), the Examiner will consider the information previously considered by the Office during examination of the parent application, even if not resubmitted by the Applicants.

37 CFR § 1.98(d) provides that legible copies need not be provided with an IDS if i) the information was submitted to the Office in a properly identified prior application that is relied upon for an earlier filing date, and ii) if the IDS filed in the prior application complied

with 37 CFR § 1.98(a)-(c). On January 17, 2003, a Form 1449 listing of citations was filed in the present case, and this form was marked received on January 22, 2003. The Amendment and Response filed on January 17, 2003 with the Form 1449 indicates that the references included on the Form 1449 were those previously considered during examination of parent Appl. Ser. No. 09/350,309. The IDS filed in parent Appl. Ser. No. 09/350,309 complied with 37 CFR § 1.98(a)-(c). Thus, in accordance with 37 CFR § 1.98(d), legible copies of the documents cited on the Form 1449 filed in the present case are not required to be submitted and the IDS filed on January 17, 2003 is compliant with the requirements of 37 CFR § 1.98.

As the present Application claims priority to a parent case in which this information was considered, and as the IDS filed in the present Application is compliant with the requirements of 37 CFR § 1.98, Applicants respectfully request that the Examiner fully consider the information disclosed on Form 1449 and indicate such consideration on the form.

***Priority***

As indicated in the New Application Transmittal and the Preliminary Amendment filed with the present application on October 18, 2001, and as acknowledged on the Filing Receipt mailed November, 15, 2001, the present application is a Continuation of U.S. Appln. Ser. No. 09/350,309, filed July 9, 1999, which is a Divisional of U.S. Appln. Ser. No. 08/756,386, filed November 29, 1996, now U.S. Patent No. 5,985,557, which is a Continuation-In-Part of U.S. Appln. Ser. No. 08/682,853, filed July 12, 1996, now U.S. Patent No. 6,001,567, which is a Continuation-In-Part of U.S. Appln. Ser. No. 08/599,491, filed January 24, 1996, now U.S. Patent No. 5,846,717.

The first paragraph of the present Application is amended to indicate that parent Appln. Ser. No. 09/350,309 has now issued as U.S. Patent No. 6,348,314. Specific reference to this priority application by serial number was made in the present Application by Preliminary Amendment made on the day of filing. As such, the claim for priority was not delayed.

***Double Patenting***

The Examiner makes several obviousness-type double patenting rejections in view of U.S. Patent Nos. 5,846,717, 6,001,567, and 6,348,314 (Office Action, pages 4-6). As each of these patents are co-owned by the present Applicants, Applicants herein file a terminal disclaimer to overcome the rejections. Applicants respectfully request that these rejections be removed.

### **35 USC § 112**

The Examiner has rejected Claims 26-35, 42, and 61-76 under 35 USC § 112, second paragraph as being indefinite. First, the Examiner asserts that these claims are indefinite in that the language of Claim 26 does not clearly describe the cleavage structure formed (Office Action at page 7). Applicants respectfully disagree. Claim 26 specifies that the structure formed is one that is cleaved by a thermostable 5' nuclease (Claim 26 at 'b'). Examples of structures that are cleaved by a thermostable 5' nuclease are both diagrammed and described throughout the specification (see, *e.g.*, Figures 16A-E, Figure 22A, Figure 29, Figure 65 A-D, Description of the Invention, *e.g.*, at Parts I (starting at page 39), III (starting at page 51), IV (starting at page 62), and VI (starting at page 69). From this information alone, one of skill in the art would be able to determine the general type of structure formed in the claimed methods. Claim 26 further recites specific features of, and relationships between, the different regions of the recited nucleic acids (*e.g.*, regions that are complementary, regions that are contiguous, 5' or 3' orientations) that form the cleavage structures of the instant claims. In view of the specification and the language of the claims, one of skill in the art would clearly be able to determine the metes and bounds of the instant Claims. As such, these Claims meet the requirements of 35 USC § 112, second paragraph and Applicants respectfully request that this rejection be removed.


The Examiner has further asserted that the term "synthetic" is indefinite in that it is unclear as to whether the scope of the term refers to fragments manually constructed through an oligonucleotide synthesizer, fragments that have been derived from biological sources through intervention of a person's hand, or whether the term refers to PCR synthesized nucleic acid (Office action page 7). Applicants respectfully disagree with the Examiner's characterization of this term, and direct the Examiner's attention to the description in the specification of various sources of target nucleic acids (page 56, lines 12-23). As indicated at

page 56, lines 19-23, a target nucleic acid "may be isolated from an organism . . . **or** it may be synthetic" (emphasis added). In other words, the term "synthetic" as used in reference to target nucleic acid indicates that the target nucleic acid is one that is generated by a method *other than* by isolation from an organism. In the same paragraph, specific reference is made to a variety of methods for generating a target nucleic acid such that it is not "isolation from an organism," *e.g.*, "[t]he target nucleic acid may also be transcribed *in vitro* from a DNA template or may be chemically synthesized or generated in a PCR." These exemplary methods comprise both chemical synthesis (*e.g.*, as would be done with an oligonucleotide synthesizer), and enzymatic synthesis, *e.g.*, with a DNA or RNA polymerase. Thus, the term "synthetic" is not indefinite and Applicants respectfully request that this rejection be removed.

#### **CONCLUSION**

For the reasons set forth above, it is respectfully submitted that all rejections should be removed and Applicants' claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: January 28, 2004

  
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